

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/568,944

**Applicant(s)**

YONEDA, TADASHI

**Examiner**

ANISH GUPTA

**Art Unit**

1654

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 24 August 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
 NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-15.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☒ Other: Attached Interview Summary.

/Anish Gupta/  
Primary Examiner, Art Unit 1654

Continuation of 11. does NOT place the application in condition for allowance because: Both art rejections of Yoneda et al. (WO99/62482) in view of Noda (JP07-304630) and Sakai et al. (JP2000136114) in view of Yoneda et al. are hereby maintained. For Both rejections, Applicants agree that separation is deemed an undesired property.

Applicants argue that the art provides that separation is deemed an undesired property. Applicants cite three US patents and publications and cite a Japanese Patent for the position that separation is an undesired property and should be avoided. Applicants argue that the Guidelines, submitted prior to the Final rejection, clearly references stability and indicates that separation should be avoided. Applicants argue that the comparative example utilized is identical to example 1, table 1 in the present specification except that the polyoxyethylene (20) sorbitan monostearate has been used, similar to formulation example 2 on page 42 of WO99/62482. Applicants state that "[w]hile the Examiner asserts that the comparison should be with Noda and Sakai, it is submitted that the purpose of the invention is to improve upon a lipopeptide composition like Yoneda. . . ." Applicants argue that the MPEP 716.02(e) allows the applicant to compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. Applicants state that the "Comparison Example in the Declaration is within the scope of Yoneda and thus can adequately represent Yoneda."

Applicants arguments have been fully considered but have not been found persuasive.

From the onset, there seems to be a differing interpretation of "stability" in the office actions and Applicants response. For the purposes of interpretation of the claims and the arguments, stability has been interpreted to mean a resistance to chemical decomposition and/or degradation. Note that the Guidelines by the CTFA, submitted by Applicants prior to the Final rejection, made reference to "chemical stability," "microbiological stability," and "physical integrity of cosmetic products." (see page 2 of the Guidelines) Based on these statements, it was assumed that stability referenced some chemical decomposition and/or degradation. However, if Applicants believe that that stability is referencing another characteristic or is defined differently from chemical decomposition and/or degradation, the Applicants should make clear the context in which "stability" has been used. Absent any specific definition, it will be assumed, much like the Guidelines by the CTFA that stability references "chemical stability," "microbiological stability," and "physical integrity of cosmetic products."

Using stability in the context of chemical decomposition and/or degradation, Applicants response does not provide evidence that separation is related to instability of the formulation. For example, Brown (US7455847) makes reference to separation for the purposes of uniform application and "aesthetic qualities." (see Col. 1, lines 50-55). The reference of Quadir et al. and Brown (utilizes insoluble agents which are not present in the references cited in the prior art rejection. None of the references cited by Applicant establish clearly and unequivocally that separation is directly related to chemical, microbiological of physical stability of the product.

Applicants argue that the MPEP allows applicant to compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. While the MPEP makes such an allowance, this does not mean that Applicant can compare a completely different product from that of the prior art. In Ex parte Humber, 217 USPQ 265 (Bd. App. 1961), the compounds tested were 9-, 12- and 14- chloro derivative. While the prior art was a 13 chloro derivative. Note that 13-chloro compound fell squarely with the tested compounds. Here, the prior art example 2, which Applicants have state is the closest to the comparative compound, contains avocado oil, behenyl alcohol, steric acid, glycerin fatty acid ester, polyoxyethylene sorbitan fatty acid ester, polyoxyethylene alkyl ether, tocopherol, magnesium ascorbic 2-phosphate, sodium ascorbic 2-phosphate, 1,3-butylene glycol, methylparaban, perfume surfactin (lipopeptide) and water. The example in the Declaration only contain sodium surfactin, glycerin, polyoxyethylene (20) sorbitan fatty acid ester, glyceryl tri(2-ethylhexonate) and water. Note that the comparative example does not contain avocado oil, behenyl alcohol, steric acid, glycerin fatty acid ester, polyoxyethylene alkyl ether, tocopherol, magnesium ascorbic 2-phosphate, sodium ascorbic 2-phosphate, 1,3-butylene glycol, methylparaban. The example in the prior art does not contain glyceryl tri(2-ethylhexonate). The two formulations are completely different. Applicant Declaration nor their arguments do not provide any explanation as to how or why the "Comparative Example," even though it is entirely different from the prior art example, would be representative for the formulations taught in Yoneda. Stated differently, given the large variance in ingredients, one of ordinary skill in the art could not conclude that the prior art formulations in example 1-36 would separate similar to the "Comparative Example." It should be noted that the same section 716.02(e) cited by Applicants also state "Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, in re Finley, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required." Here, Applicants have not provided an explanation of the deviations.

Finally, with respect to Sakai et al. reference, the "comparative example" is simply not relevant. Note that Sakai et al. teaches a formulation in which polyoxyethylene glyceryl fatty acid ester is already present. Thus, the separation observed in Yoneda "comparative example" would not be observed for Sakai. In essence, the statements made in the Declaration with regards to separation and stability are not relevant to Sakai.

Rejections are maintained.